

**DR. COCOA NIGHTTIME COUGH AND COLD- diphenhydramine hydrochloride, phenylephrine hydrochloride liquid**  
**Infirst Healthcare**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Dr. Cocoa Nighttime Cough+Cold**

**Drug Facts**

**Active ingredients**

**(in each 5 mL)**

Diphenhydramine HCl 6.25 mg

Phenylephrine HCl 2.5 mg

**Purpose**

Antihistamine/Cough suppressant

Nasal decongestant

**Uses**

- temporarily relieves:
- sneezing
- runny nose
- itchy nose or throat
- itchy, watery eyes
- cough due to minor throat and bronchial irritation as may occur with a cold
- nasal congestion

**Warnings**

**Do not use**

- to make a child sleepy
- in a child under 6 years of age
- with any other drug containing diphenhydramine, even one used on the skin
- in a child now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before using this product.

**Ask a doctor before use if your child has**

- heart disease

- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- trouble urinating due to an enlarged prostate gland
- breathing problems such chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use** if your child is taking sedatives or tranquilizers

### **When using this product**

- **do not use more than directed**
- excitability in your child may occur
- marked drowsiness in your child may occur
- sedatives and tranquilizers may increase drowsiness

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with a fever
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

**Keep out of reach of children. Dr. Cocoa™ is a medicine.** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

### **Directions**

- shake well before use
- measure only with the provided double-ended dosing spoon
  - read dosing spoon carefully and select the correct spoon
  - large dosing spoon holds 5 mL when filled to the top rim
  - small spoon holds 2.5 mL when filled to the top rim
  - do not use dosing spoon with other products
  - dose as follows or as directed by a doctor
- mL = milliliter

<b>Age (year)</b>	<b>Dose (mL)</b>
children 12 and 13 years of age	20 mL every 4 hours; do not take more than 120 mL in 24 hours
children 6 to under 12 years of age	10 mL every 4 hours; do not take more than 60 mL in 24 hours
children under 6 years of age	do not use

**Other information**

- each 5 mL contains: **sodium 7 mg**
- store at 20 - 25°C (68 -77°F)

**Inactive ingredients**

anhydrous citric acid, cocoa, maltitol, methylparaben, natural flavor, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate

**Questions or comments?**

call **1-855-848-3284** toll free

**PRINCIPAL DISPLAY PANEL - 120 mL Bottle Label**

**Dr.**

**Cocoa™**

.....

**for Children**

**Nighttime**

**Cough+Cold**

Diphenhydramine HCl

(Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

For Ages

6-13

4 FL OZ (120 mL)

**Active ingredients (in each 5 mL)**

Diphenhydramine HCl 6.25 mg . . . . . Antihistamine/Cough suppressant

Phenylephrine HCl 2.5 mg . . . . . Nasal decongestant

**Uses:** temporarily relieves ■ sneezing ■ runny nose ■ itchy nose or throat ■ itchy, watery eyes ■ cough due to minor throat and bronchial irritation as may occur with a cold ■ nasal congestion

**Warnings:** Do not use ■ to make a child sleepy ■ in a child under 6 years of age ■ with any other drug containing diphenhydramine, even one used on the skin ■ in a child now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your child's prescription drug contains an MAOI, ask a doctor or pharmacist before using this product. Ask a doctor before use if your child has ■ heart disease ■ diabetes ■ high blood pressure ■ thyroid disease ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ breathing problems such as chronic bronchitis ■ persistent or chronic cough such as occurs with asthma ■ cough that occurs with too much phlegm (mucus) Ask a doctor or pharmacist before use if your child is taking sedatives or tranquilizers. When using this product ■ do not use more than directed ■ excitability in your child may occur ■ marked drowsiness in your child may occur ■ sedatives and tranquilizers may increase drowsiness. Stop use and ask a doctor if ■ nervousness, dizziness,

or sleeplessness occur ■ symptoms do not improve within 7 days or occur with a fever ■ cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. Keep out of the reach of children. Dr. Cocoa™ is a medicine. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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**Questions or comments?** call 1-855-846-3284 toll free

Manufactured for: Infirst Healthcare Inc., Westport, CT 06880  
©2014 Infirst Healthcare Inc.

Tamper evident: DO NOT USE if seal under cap imprinted with "Sealed for Your Protection" is broken or missing.

LOT:
EXP:

## PRINCIPAL DISPLAY PANEL - 120 mL Carton

NDC 62372-743-04

**NEW!**

**Dr.**

**Cocoa™**

.....

**for Children**

**Nighttime**

**Cough+Cold**

Diphenhydramine HCl

(Antihistamine/Cough Suppressant)

Phenylephrine HCl (Nasal Decongestant)

Relieves:

Cough

Stuffy Nose

Runny Nose

Sneezing

*Helps Your*

*Child Rest*

For Ages 6-13

# Real Chocolate Taste

4 FL OZ (120 mL)



**Dr. Cocoa™**  
for Children

**Nighttime  
Cough+Cold**

Tamper evident: DO NOT USE if seal under cap imprinted with "Sealed for Your Protection" is broken or missing.

NDC 62372-743-04

**NEW!**

**Dr. Cocoa™**  
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**Nighttime  
Cough+Cold**

Diphenhydramine HCl  
(Antihistamine/Cough Suppressant)  
Phenylephrine HCl (Nasal Decongestant)

Relieves:  
**Cough  
Stuffy Nose  
Runny Nose  
Sneezing**  
Helps Your  
Child Rest



For Ages 6-13  
**Real Chocolate Taste**

4 FL OZ (120 mL)

## Drug Facts (continued)

Keep out of the reach of children. Dr. Cocoa™ is a medicine. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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**infirst<sup>+</sup>**  
HEALTHCARE

Manufactured for:  
infirst Healthcare Inc.  
Westport, CT 06880  
©2014 infirst Healthcare Inc.  
US 8,348,470. Patent Pending

**Dr. Cocoa™**  
for Children

Kids hate feeling sick. But they also hate taking medicine that doesn't taste good. That's why there's Dr. Cocoa™

Your child will love the rich, soothing, real cocoa flavor, and you'll love the relief it provides. Dr. Cocoa is dye free, alcohol free, and gluten free, plus the active ingredients are proven to relieve cough and cold symptoms. Your child can get a good night's sleep—and so can you.

Dr. Cocoa for Children is also available in these formulas



Please visit our website at:  
[www.DrCocoa.com](http://www.DrCocoa.com)

Dye Free • Alcohol Free • Gluten Free

## Drug Facts

Active ingredients (in each 5 mL)	Purpose
Diphenhydramine HCl 6.25 mg	Antihistamine/Cough suppressant
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## Uses

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  - glaucoma
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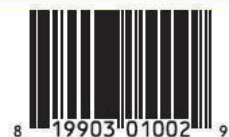
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**DR. COCOA NIGHTTIME COUGH AND COLD**

diphenhydramine hydrochloride, phenylephrine hydrochloride liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62372-743
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	6.25 mg in 5 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	2.5 mg in 5 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)	
<b>COCOA</b> (UNII: D9108TZ9KG)	
<b>MALTITOL</b> (UNII: D65DG142WK)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62372-743-04	1 in 1 CARTON	12/20/2014	
1		120 mL in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/20/2014	

**Labeler -** Infirst Healthcare (079159739)

**Registrant -** Woodfield Pharmaceutical, LLC (079398730)

## Establishment

Name	Address	ID/FEI	Business Operations
Woodfield Pharmaceutical, LLC		079398730	manufacture(62372-743)

Revised: 11/2021

Infirst Healthcare